

## **REMARKS**

The Office Action mailed December 9, 2003 has been received and the Examiner's comments carefully reviewed. The specification was amended to more clearly reflect the invention; the amendments are supported through the specification itself and also at FIGS. 13-19. Proposed drawing amendments, which more clearly depict the invention without adding any new subject matter, are included herewith. Claims 1-17 and 20-27 have been canceled without prejudice. Claims 18, 28, 33, 35-38, 44-45, 48, 50, 51, 57-58, and 63 have been amended to more clearly recite the invention. Claims 67-70 have been added. The amendments and the new claims are directed at the distal end of the instrument guide and are supported at FIGS. 13-19 and at page 12, line 7 through page 15, line 25. No new matter has been added. Applicants respectfully submit that the pending claims are in condition for allowance.

### **A. Drawing**

Applicants propose to amend Figures 13, 14, 15 and 18. The particular amendments are described in the Proposed Amendment to the Drawing section. In addition, attached hereto are clean and red-line copies of the above identified amend figures. As discussed in the Proposed Amendment to the Drawing section, the proposed amendments add no new subject matter.

### **B. Obvious-type Double Patenting Rejection**

Claims 18, 19, 50, 51, 55, 56, 57, 58, and 62 were rejected under the doctrine of obviousness-type double patenting over claim 8 of U.S. Pat. No. 6,626,905 to Schmiel et al. in view of U.S. Pat. No. 5,803,904 to Mehdizadeh (the '904 patent).

Claim 8 of Schmiel et al. recites steps of a surgical procedure, but does not claim the instrument used in that procedure. In contrast, the above-listed claims recite an instrument used in a surgical procedure. Though Mehdizadeh '904 does disclose a surgical instrument, it does not disclose a surgical instrument according the above-listed claims. All of the above-listed claims recite a tube with a distal edge having an angle of about 10° to about 45° relative to a reference line perpendicular to the longitudinal axis of the tube. In contrast, the '904 patent discloses a tube having a distal edge oriented at a much greater angle relative to a reference line perpendicular to the longitudinal axis of the tube. Based upon Figure 3, it appears that the angle

of the distal edge 29 is approximately 70° to 80° relative to a reference line perpendicular to the longitudinal axis of the tube. Moreover, the '904 patent teaches that the cutaway portion 29 at the distal end, which defines the distal edge angle, is designed to allow the surgeon visual access to the operating area. See the '904 patent at column 1, lines 29-44; at column 3, lines 9-10; and at column 3, lines 32-37. Therefore, since an angle between 10° to 45° would not provide visual access as well as an angle greater than 45°, the '904 patent teaches away from modifying the device to include a distal edge with an angle between 10° to 45° relative to a reference line perpendicular to the tube's longitudinal axis. Accordingly, the above-listed claims are not obvious over claim 8 of Schmiel et al. in view of the '904 patent.

### **C. Anticipation**

#### **1. Claims 28, 29, 31, and 32**

Claims 28, 29, 31, and 32 were rejected under 35 U.S.C. 102(b) as being anticipated by the '904 patent. The above-listed claims all recite an instrument guide comprising a tube having a distal edge positioned between 10° to about 45° relative to a reference line perpendicular to the tube's longitudinal axis.

As discussed above, the '904 patent fails to disclose such structure. Instead, the '904 patent discloses a distal edge oriented at a much greater angle relative to a reference line perpendicular to the tube's longitudinal axis. See the '904 patent at Figure 3 and at column 1, lines 29-44; at column 3, lines 9-10; and at column 3, lines 32-37 (stating that the cutaway is sized and configured to allow visual access to the working area). Accordingly, claims 28, 29, 31, and 32 are not anticipated by the '904 patent.

#### **2. Claims 28, 29, 31, 32, 37, 39, and 40**

Claims 28, 29, 31, 32, 37, 39, and 40 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,030,390 to Mehdizadeh (the '390 patent). The above-listed claims all recite an instrument guide comprising a tube having a distal edge positioned about 10° to about 45° relative to a reference line perpendicular to the tube's longitudinal axis.

Since the '390 patent simply references the disclosure in the '904 patent with respect to the tag retractor 22 shown in Figure 3, which is the subject of this rejection, in accordance with

the arguments made above, the '390 patent also fails to anticipate claims 28, 29, 31, 32, 37, 39, and 40. See the '390 patent at column 2, line 62 through column 3, line 3.

### 3. Claims 28-32 and 35

Claims 28-32 and 35 were rejected under 35 U.S.C. 102(b) as being anticipated by Bryan (5,306,275). The above-listed claims all recite an instrument guide comprising a tube having a distal edge positioned about 10° to about 45° relative to a reference line perpendicular to the tube's longitudinal axis.

Bryan fails to teach the structure described above. Instead, Bryan discloses a burr guide that includes a pair of opposed cutouts 133 and 134 at a distal end that are designed to straddle the saddle in the vertebra between the spinous process 103 and the transverse process 106 immediately above the pedicle 108. See Bryan at column 14, lines 29-53. Neither the written description nor any of the figures disclose or teach the inclusion of a distal edge positioned at about 10° to about 45° relative to a reference line perpendicular to the tube's longitudinal axis as recited in the above-listed claims.

## **D. Obviousness**

### 1. Claims 33 and 34

Claims 33 and 34 were rejected under 35 U.S.C. 103(a) as being obvious over the '904 patent. Claims 33 and 34 depend on claim 28, which recites an instrument guide comprising a tube having a distal edge positioned about 10° to about 45° relative to a reference line perpendicular to the tube's longitudinal axis.

As discussed above, the '904 patent discloses a tube that has a distal edge oriented at a much greater angle relative to a reference line perpendicular to the tube's longitudinal axis. See Figure 3. The '904 patent teaches that the cutaway portion 29 at a distal end, which defines the distal edge angle, is designed to allow the surgeon visual access to the operating area. See the '904 patent at column 1, lines 29-44; at column 3, lines 9-10; and at column 3, lines 32-37. As discussed above, since an angle less than 45° would not provide visual access as well as an angle that is greater than 45°, the '904 patent teaches away from modifying its claimed device to include a distal edge with an angle between 10° to 45° relative to a reference line perpendicular

to the tube's longitudinal axis. Accordingly, the above-listed claims are not obvious over the '904 patent.

## 2. Claims 33, 34, 36, 50, 51, 55-58, 62, 63 and 66

Claims 33, 34, 36, 50, 51, 55-58, 62, 63 and 66 were rejected under 35 U.S.C. 103(a) as being obvious over Bryan. Again, the above-listed claims all recite an instrument guide comprising a tube having a distal edge positioned within about 10° to about 45° relative to a reference line perpendicular to the tube's longitudinal axis.

As discussed above, Bryan fails to teach or suggest such structure. Rather, Bryan discloses a burr guide that includes a pair of opposed cutouts 133 and 134 at the distal end of a tube that are designed to straddle the saddle in the vertebra between the spinous process 103 and the transverse process 106 immediately above the pedicle 108. See Bryan at column 14, lines 29-53. Neither the written description nor any of the figures teach or suggest the inclusion of a distal edge positioned about 10° to about 45° relative to a reference line perpendicular to the tube's longitudinal axis. Furthermore, there is no suggestion that providing a distal edge in the range of 10° to about 45° would improve the device's ability to straddle the saddle of the vertebra. Accordingly, Bryan provides no motivation to provide an angled distal edge as claimed. Consequently, the above-listed claims are not obvious over Bryan.

## 3. Claims 42-66

Claims 42-66 were rejected under 35 U.S.C. 103(a) as being obvious over the '904 patent in view of Bryan. Again, the above-listed claims all recite an instrument guide comprising a tube having a distal edge positioned within about 10° to about 45° relative to a reference line perpendicular to the tube's longitudinal axis. As discussed above, neither the '904 patent nor Bryan disclose or suggest such structure. Accordingly, the above-listed claims are not obvious over the '904 patent in view of Bryan.

The new claims 67-70 include, among other things, the angled portion referenced in detail above. Consequently, they are patentable over the cited references, for at least the same reason discussed above.

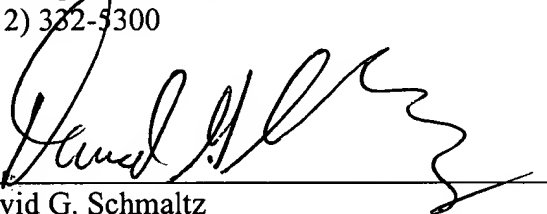
In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the 612-336-4617.

Respectfully submitted,

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PATENT TRADEMARK OFFICE



Inventor: Schmiel et al.  
Docket No.: 6683.47US11  
Title: Reply to Office Action of December 9, 2003  
Serial No.: 09/921,008  
ANNOTATED SHEET

FIG. 12

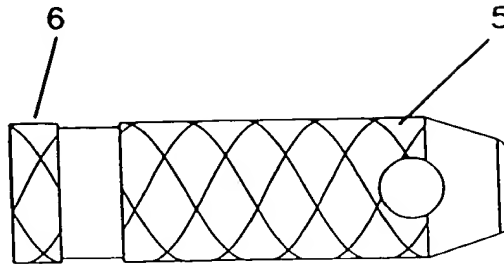


FIG. 15

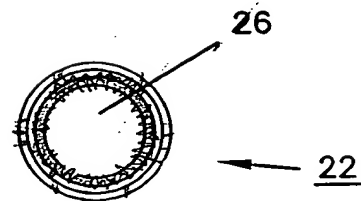




FIG. 13

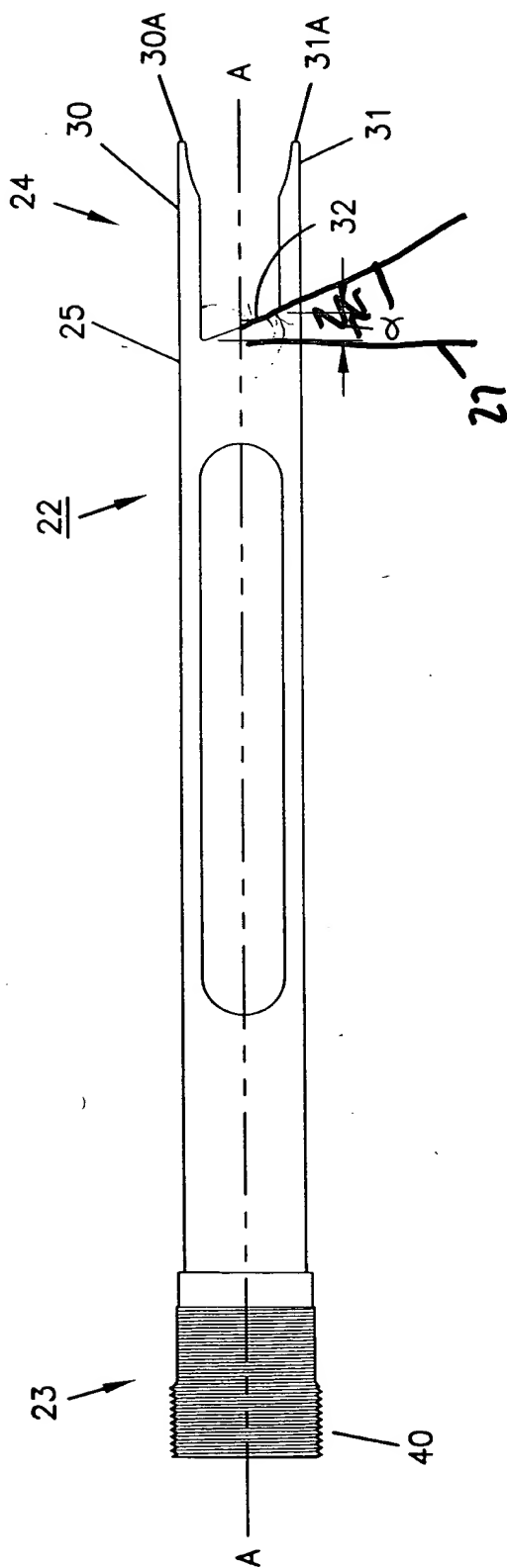
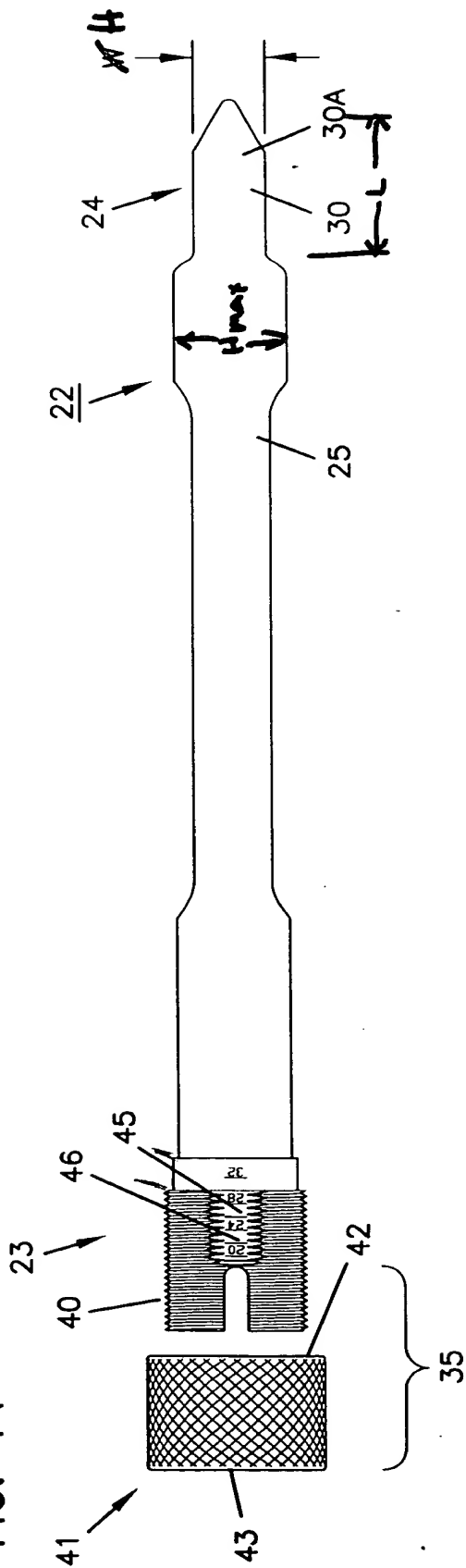


FIG. 14





Inventor: Schmiel et al.  
Docket No.: 6683.47US11  
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FIG. 18

